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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,275	03/28/2007	Ryozo Nagai	P30563	2170

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EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
11/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No.	Applicant(s)	
	10/598,275	NAGAI ET AL.	
	Examiner	Art Unit	
	CHARLESWORTH RAE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-6,8,17-19 and 21-32* is/are pending in the application.

4a) Of the above claim(s) *22-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6, 8, 17-19, and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *22-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 07/28/08, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

This action is made final.

Status of the Claims

Claims 3-6, 8, 17-19, 21-32 are currently pending in this application.

Claims 21-32 are new.

Claims 22-32 are withdrawn from examination for being constructively non-elected by original presentation.

Claims 3-6, 8, 17-19 and 21 are under examination.

Miscellaneous

It is noted that there is an inadvertent typographical error in the patent number (US Patent 5,820,057 i.e. Muto) in the rejection under 102(b) (see Office action, mailed 2/27/08, pages 4-6). The correct patent number is US Patent 5,852,057, which was correctly cited on Form 892 that accompanied the Office action mailed 02/27/08. In view of the fact that applicant understood the correct patent reference the examiner was referring to in the action, the examiner retains the right to make the instant Office action final.

Election by Original Presentation

Newly submitted claims 22-32 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Invention I: Claims 3-6, 8, 17-19 and 21, drawn to a composition, classified in class 424, subclass 63.

Invention II: Claim 60, drawn to a method of inhibiting vascular remodeling, , classified in class 424, subclass 63.

Inventions I-II are directed to a product and related process of using said product. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, invention I as claimed may be practiced by a materially different process e.g. a method for treating cancer. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-32 are withdrawn from consideration

as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to applicant's arguments/remarks

Rejection under 102(b)

Applicant's arguments are not found to be persuasive to overcome the rejection of record because the instant claimed compounds/compositions are anticipated by the prior. Further, the compounds/compositions of the cited are capable of performing the intended claimed functions (see applicant's Response, pages 9-10).

Rejection under 102(e)

Applicant's arguments are not found to be persuasive to overcome the rejection of record because the instant claimed compounds/compositions are anticipated by the prior. Further, the compounds/compositions of the cited are capable of performing the intended claimed functions (see applicant's Response, pages 6-8).

REJECTIONS

Claim rejections- 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

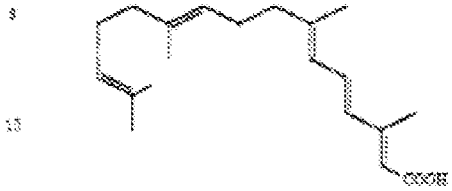
(b) the invention was patented or described in a printed publication in this or a foreign

country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-6, 8, 17-19, and 21 are rejected under 35 USC 102(b) as being anticipated by Muto (US Patent 5,852,057).

Claim 3 recites "[a] medicament having an inhibitory action against arteriosclerosis caused by vascular injury, the medicament comprising an acyclic polyprenyl compound as an active ingredient, and a pharmaceutically acceptable additive." Claim 4 recites "wherein the acyclic polyprenyl compound is a polyprenylcarboxylic acid." Claim 5 recites "wherein the acyclic polyprenyl compound is 3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentanoic acid." Claim 6 recites "wherein the acyclic polyprenyl compound is (2E,4E,6E, 10E)-3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentanoic acid." Claims 8, 17, 18, and 19 recites "which is in the form of a pharmaceutical composition for oral administration."

Muto (US Patent 5,852,057) teaches the below compound, 3,7,11,15-tetramethyl- 2,4,6,10,14-hexadecapentaenoic acid, is an acyclic retinoid (polyprenoic acid) compound and is preferentially contained as a major component in the anticarcinogenic pharmaceutical composition in the form of a crystalline powder (col. 2, lines 1-48):



or a salt thereof and a pharmaceutically acceptable carrier.

3,7,11,15-Tetramethyl-2,4,6,10,14-hexadecapentaenoic acid is an acyclic retinoid (polyprenoic acid) and is preferably contained as a major component (at least 50 wt %, preferably, at least 80 wt %) in the anticarcinogenic pharmaceutical composition of the present invention. 3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentaenoic acid is a crystalline powder with a white to lemon yellow color and is odorless. This compound functions to effectively prevent the occurrence of hepatocellular carcinoma (the occurrence of a second primary tumor), occurrence of hepatocellular carcinoma in high risk groups with chronic hepatitis and liver cirrhosis, and occurrence of cervical carcinoma intraepithelialis, lung adenocarcinoma, lung squamous cell carcinoma, mammary tumors, and the like, in cell lines of the carcinoma. The compound also has relatively low toxicity.

Any pharmaceutically acceptable salt of 3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentaenoic acid may also be used.

The above compounds read on the instant claimed compounds. Muto also teaches compositions (i.e. capsules containing 150 mg of an above referenced compound with an excipient) for oral administration (col. 3, lines 6-9; and reference claim 5), which reads on instant claims 3, 8, 17, 18, and 19 as these claims recite the term “which is in the form of a pharmaceutical composition for oral administration.”

With respect to the preamble and the intended use limitations, the cited art teaches applicant's claimed compounds and therefore one would reasonably expect that the compound(s) taught by the cited art would have the same therapeutic utility,

including having an inhibitory action against arteriosclerosis caused by vascular injury and vascular injury caused by vascular reconstructive surgery.

For the above reasons claims 3-6, 8, 17-19, and 21 are deemed to be anticipated by the cited prior art.

Claims 3-6, 8, 17-19, and 21 are rejected under 102(e) as being anticipated by Shidoji et al. (US Patent 2005/0250671).

Shidoji et al. (US Patent 2005/0250671) teach the exact polyprenyl acyclic compound recited in claim 6 i.e. (2E,4E,6E,10E)-3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentaenoic acid (Development Code: "NIK-333"); see para 0006). The compound as taught by the cited art also reads on the acyclic polyprenyl compounds encompassed by claims 3, 4, 5, 8, 17, 18, 19 and 21. Shidoji et al. also teach other examples of polyprenyl compounds, including conjugated polyprenylcarboxylic acids (polyprenoic acids) such as 3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentaenoic acid and esters thereof (para 0016), which reads on the compound recited in claim 5.

The term “a pharmaceutically acceptable additive" as recited in claim 3 is found in the cited reference which teaches desired pharmaceutical compositions can be prepared by using pharmaceutical carriers and excipients ((para 0019).

With respect to the preamble and the intended use limitations, the cited art teaches applicant's claimed compounds and therefore one would reasonably expect

that the compound(s) taught by the cited art would have the same therapeutic utility, including having an inhibitory action against arteriosclerosis caused by vascular injury and vascular injury caused by vascular reconstructive surgery.

For the above reasons, claims 3-6, 8, 17-19, and 21 are found to be anticipated by the cited art.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau, can be reached at 571-272-0614. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

2 November 2008
/C. R./
Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611